

# Notice of Allowability

Application No.

10/087,667

Examiner

Joseph T. Voitach

Applicant(s)

BRAMLEY ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to August 16, 2004.
2. ☒ The allowed claim(s) is/are 65-78.
3. ☒ The drawings filed on 28 February 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### **DETAILED ACTION**

This application is a continuation in part of 09/337,079, filed June 21, 1999, now abandoned, which claims benefit to provisional application 60/090,175 filed June 22, 1998.

Applicants' amendment filed August 16, 2004, has been received and entered. The specification has been amended. Claims 1-64 have been canceled. Claims 65-78 have been added. Claims 65-78 are pending and currently under examination.

### ***Election/Restrictions***

Applicant's election of Group VII, drawn to a non-human transgenic mammal comprising an altered non-mammalian lysostaphin gene, was acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

It was noted previously that upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. No linking claims have been added in the current amendment.

All newly added claims are drawn to the elected invention and under examination as they are drawn to the invention of a non-human transgenic mammal comprising an altered non-mammalian lysostaphin gene.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Information Disclosure Statement***

The information disclosure statement filed August 16, 2004, has been received and considered. The references present in 09/337,079 have been considered. A newly signed and initialed copy of the IDS forms is provided with the instant action.

***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance:

Newly added claims include specific limitations that address each of the specific basis of rejection made under 35 USC 112, first paragraph. Specifically, the claims have been amended to reflect that an active form of lysostaphin is expressed and recite embodiments of a promoter and secretion signal wherein expression of lysostaphin occurs in the mammary gland in amounts detectable in the milk. The expression of functional proteins in the mammary gland of a non-human mammal were well known at the time of filing. Further, the antibacterial properties of lysostaphin were known and characterized as the time of filing, however the present disclosure is the first to demonstrate that alterations to the protein resulting in modification to the glycosylation of lysostaphin would not adversely affects it properties and result in a functional

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protein when expressed by a cell. While the two essential elements of the claim were known at the time of filing, the art fails to provide the specific motivation to combine the elements into the invention instantly claimed. Moreover, the present disclosure is the first to demonstrate that altering the glycosylation pattern does not adversely affect the function of lysostaphin. This disclosure would not have been necessarily expected based on the importance of glycosylation in some proteins known at the time of filing, and the general unpredictability in the art for making modifications to a protein while preserving function of the expressed protein.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

JOSEPH WOITACH  
PATENT EXAMINER

*Joe Woitach*  
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